

# **Exhibit 296**

## **(Filed Under Seal)**



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK

Plaintiff,

v.

ACTAVIS, PLC, and  
FOREST LABORATORIES, LLC,

Defendants.

Case No.: 14-cv-7473

**FILED UNDER SEAL**

**DECLARATION OF ROBERT STEWART**

I, Robert Stewart, hereby declare as follows:

1. I am the Chief Operating Officer of Actavis, plc. I assumed the position of Chief Operating Officer as of July 1, 2014. Previously, I served as Actavis's President, Global Operations, and I have worked at Actavis or Watson Pharmaceuticals (which acquired Actavis but took the "Actavis" name) in various capacities since 2009.

**Summary of Testimony**

2. For the reasons set forth below, I declare as follows:

- Manufacturing yield issues in production batches of NAMENDA XR® extended release capsules complicated Forest's decisions concerning the timing of the discontinuation of twice-a-day immediate release NAMENDA® 5 mg and 10 mg tablets and transition to once-a-day NAMENDA XR®.
- Because of the NAMENDA XR® continuing yield issues, [REDACTED] Forest announced on June 10, 2014 that it would continue to market the NAMENDA® tablets into the fall of 2014.
- Actavis was able to utilize its high-volume world-class manufacturing resources and experience to work with Forest on the yield issue. [REDACTED] have dramatically increased production batch yields.
- Forest believes it has sufficiently resolved the manufacturing yield issues for NAMENDA XR® and can meet demand going forward. Additionally, Forest recently released a large bolus of NAMENDA XR® tablets for sale.

**DX717**



## **Background**

3. I am familiar with Actavis's manufacturing facilities and capabilities. I am personally aware of Actavis's manufacturing facilities and capabilities related to capsule forms of medications, including extended-release capsule formulations.

4. After Actavis's decision to acquire Forest was announced on February 18, 2014, I was involved in pre-merger integration work with the Forest team. [REDACTED]

[REDACTED] On July 1, 2014, Actavis acquired Forest Laboratories, Inc. Following the acquisition, I became responsible for Forest's product line, including Forest's memantine hydrochloride (HCL) product, including NAMENDA® and NAMENDA XR®, both of which are indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

## **Forest's Manufacturing Yield Issues for Namenda XR**

5. As part of the drug approval process, the FDA reviews and approves, among other things, a drug manufacturer's proposed manufacturing specifications for the drug product under review. [REDACTED]

6. [REDACTED]

## **Effect on Timing For Discontinuing General Distribution of Namenda® (IR) Tablets**

7. On February 14, 2014, Forest Laboratories, Inc. issued a press release announcing "plans to discontinue the sale of NAMENDA® (memantine HCl) 5 mg and 10 mg tablets," i.e., NAMENDA®IR tablets, "effective August 15, 2014." The press release explained that "[t]he oral solution of NAMENDA® and once-daily NAMENDA XR® (memantine HCl) extended-release capsules will continue to be available."

8. [REDACTED]

9. [REDACTED]



[REDACTED]

10. On June 10, 2014, Forest issued a press release announcing that it was pushing back the discontinuation of NAMENDA® IR tablets until Fall 2014. This announcement was due, in significant part, to increasing demand for NAMENDA XR® coupled with the then-continuing manufacturing yield issues for NAMENDA XR®.

11. As a result, Forest became unable to meet the then-existing market demand for NAMENDA XR, and the product was placed on "backorder" such that, for example, certain pharmacies experienced temporary backorders for NAMENDA XR®. Forest informed the FDA of this issue and, on or about August 6, 2014, the FDA added NAMENDA XR® to its Current Drug Shortage List. To date, NAMENDA XR® remains on FDA's Current Drug Shortage List.

**Yields for NAMENDA XR® Have Improved Significantly** [REDACTED]

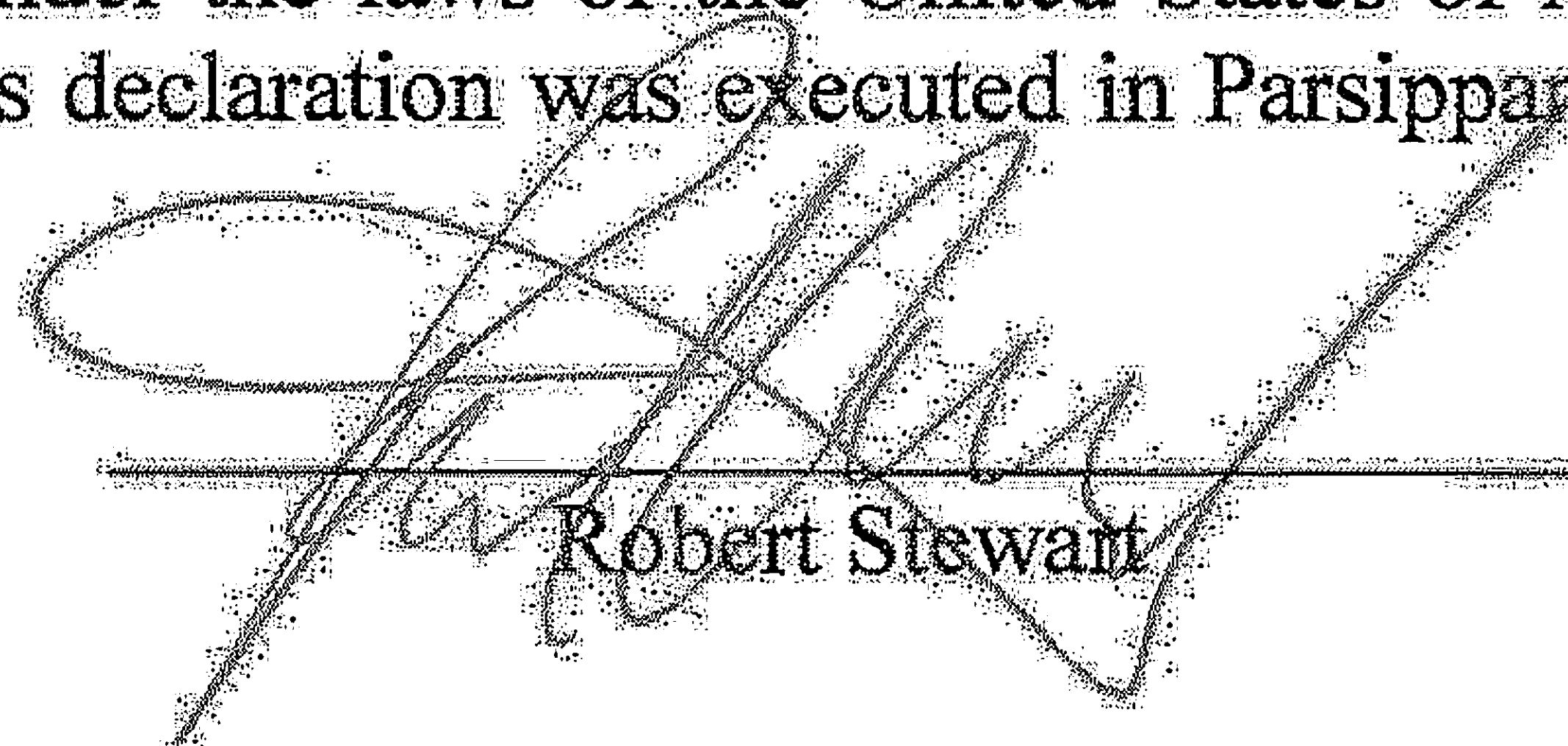
12. Following the July 1, 2014 merger, Forest and Actavis worked diligently together throughout the summer of 2014 to address the NAMENDA XR®, yield issues. [REDACTED]

[REDACTED]

13. [REDACTED]

[REDACTED] Today, Forest now has sufficient capacity to manufacture sufficient NAMENDA XR® to supply demand for all patients taking any memantine HCL therapy, including all patients taking NAMENDA® and NAMENDA XR®, when (and if) Forest discontinues the sale of NAMENDA® IR tablets. Actavis now believes that it has sufficiently resolved the yield issues for NAMENDA XR® to meet the market demand. Additionally, Forest recently released a large bolus of NAMENDA XR® tablets for sale, which should help reduce the current backorder for NAMENDA XR®.

I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration was executed in Parsippany, New Jersey on October 21, 2014.

  
Robert Stewart